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Approved:
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Reporting Guide for Laser Light Shows and Displays (21 CFR 1002)

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

FOOD AND DRUG ADMINISTRATION
Center for Devices and
Radiological Health
Rockville, Maryland 20857

The reporting and/or recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Federal Reports Act of 1942.

HE 20.4608:

READEX

INTRODUCTION

This guide is to be used for reporting Class III and IV laser light shows or displays only. Laser projectors used in such light shows or displays are to be reported using the guide titled "Guide for Submission of Information on Lasers and Products Containing Lasers Pursuant to 21 CFR 1002.10 and 1002.12." These guides are intended to assist manufacturers in providing the information the Bureau of Radiological Health needs to determine how Class III and IV laser light shows comply with the Federal Standard for laser products (21 CFR 1040.10) and with the conditions of an approved variance which is required prior to the sale, lease or use of a Class III or IV laser light show.

A report is to be submitted for each unique laser light show or display. Changes or minor variations in a previously reported light show or display are to be reported as a supplement.

If you later plan to add effects to the show reported or introduce a material change, you should submit a supplementary report describing the additions or changes. If you plan to introduce a show that is substantially different, you should submit a model change report. Such reports must be submitted prior to introduction of the changes. Attachments required by the guide should be numbered as the paragraph of the guide which requests the information being attached. For example, the information requested by item 9.0 should be numbered 9.0.

Submit your report to Director, Office of Compliance, HFZ-300, Center for Devices and Radiological Health, 8757 Georgia Ave., Silver Spring, MD 20910. You may direct questions to Optical Radiation Products Section, Consumer Industrial Products Branch, at 301-427-8228.

REPORT ON LASER LIGHT SHOW OR DISPLAY*

1.0 Identification of manufacturer

1.1 Manufacturer

(a) Name of the manufacturer _____

(b) Address _____
_____ Zip code _____

(c) Area code and telephone ( ) _____

(d) Name, signature and title of person preparing this report.

Name _____

Signature _____

Title _____

1.2 Importer (if applicable)

(a) Name of the importer
_____

(b) Address _____
_____ _____ Zip code _____

(c) Area code and telephone ( ) _____

(d) Name, signature and title of person preparing this report.

Name _____

Signature _____

Title _____

2.0 Identification of report

2.1 Is this report pursuant to para (c) of 21 CFR 1002.61?
YES___ NO___

2.2 Is this an initial report___, model change report___, or a supplemental report___?

*Information on laser projectors is to be submitted using "Guide for Submission of Information on Lasers and Products Containing Lasers Pursuant to 21 CFR 1002.10 and 1002.12."

2.3 If this is a supplemental report, give BRH accession number and date of the initial or model change report that it supplements.

Accession number_____

Date_____

2.4 Date of this report_____

3.0 What is the name(s) of the light show or display?

_____

_____

_____

4.0 Attach copy of your variance application (FDA Form 3147) and, when applicable, your approved variance.

5.0 List each projector used in the light show by manufacturer, model number or other designation, and BRH accession number (if known).

Manufacturer	Model or designation	BRH accession number

6.0 The laser light show or display takes place in a:

___ Planetarium or other dome projection structure
___ Theater
___ Discotheque or night club
___ Pavilion
___ Indoor arena
___ Museum
___ Outdoor unenclosed area
___ Other (specify)_____

_____

7.0 The laser light show or display takes place:

___ at only one (fixed) location
___ at a variety of (tour) locations
___ other (specify)_____

_____

8.0 The laser light show uses the following laser effects:

___ front screen projections
___ rear screen projections
___ holographic displays
___ multiple reflections (multiple channel or diffraction effects)
___ audience scanning
___ reflections from stationary mirror(s) or mirrored surfaces
___ stationary irradiation of rotating mirror ball(s) or other mirrored shapes
___ scanning irradiation of rotating mirror ball(s)
___ fiber optic projections
___ fog, smoke or other scattering effects
___ other (specify)_____

9.0 Provide both plan and elevation drawings with dimensions of the show or display. If the setup varies from show to show, then provide this information for a typical show. Include in the drawings the location of the projector(s) and control panel(s), audience, performer(s), operator(s), mirrors, mirror balls, display screens (or other targets) and beam termination points. Show the direct and reflected laser radiation beam paths. Provide the laser radiation levels in each beam including the wavelengths, peak and average power and scan parameters (if scanned) for the worst case from a human access point of view. Be sure the drawings indicate the minimum separations of the laser radiation fields (or beams) from reference locations in audience and performer areas in both vertical and horizontal directions and any direct or reflected beams into audience or performer locations.

Drawings attached_____

10.0 Describe how each of the laser radiation levels, indicated above, were determined. If any levels were derived from calculations rather than directly measured, provide the actual calculations which were made.

DESCRIPTION AND CALCULATIONS ENCLOSED_____

11.0 (a) Are laser radiation levels, at locations where the audience is located, maintained within the limits of Class I as a result of scanning?
YES___ NO___

If yes, describe in detail the operation of the scan failure safeguard(s). Include discussion of the detection of the scanning, the theory of operation and the speed of response of the safeguard.

DESCRIPTION ATTACHED_____

If not attached, explain_____

_____

(b) Is laser radiation intended to be viewed by operators, performers or other employees maintained with the limits of Class I as a result of scanning?
YES___ NO___

If yes, describe in detail, the operation of the scan failure safeguard(s). Include discussion of the detection of the scanning, the theory of operation and the speed of response of the safeguard.

DESCRIPTION ATTACHED_____

If not attached, explain_____

_____

(c) Are laser radiation levels not intended to be viewed in locations where operators, performers, or other employees may be present maintained within the limits of Class II as a result of scanning?
YES___ NO___

If yes, describe, in detail, the operation of the scan failure safeguard(s). Include a discussion of the detection of scanning, the theory of operation and the speed of response of the safeguard.

If no, describe in detail the means employed to prevent exposure to levels exceeding the limits of Class II.

DESCRIPTION ATTACHED_____

If not attached, explain_____

_____

12.0 Is the show under the continuous control of an operator?
YES___ NO___

12a. Does the laser operator perform tasks in addition to operation of the laser projector?
YES___ NO___

If so, describe those tasks._____

12b. Can the operator see the propagating beam paths, their terminations and the audience at all times during the performance?
YES___ NO___

12c. Do any other personnel assist in providing surveillance of the laser display?
YES___NO___

If so, state number of persons, their identification and how they assist providing surveillance.

INFORMATION ATTACHED_____

If not attached, explain_____

_____

12d. What qualifications are required of laser operators for your show?_____

_____

13.0 If your show is not under the continuous control of an operator, is a person designated to be responsible for the immediate termination of the laser radiation in the event of equipment malfunction, audience unruliness or other unsafe conditions?
YES___ NO___

How is this person designated?_____

_____

What qualifications are required?_____

_____

14.0 Are one or more readily accessible controls provided to immediately terminate laser radiation?
YES __ NO___

NUMBER OF CONTROLS_____

Describe the location of these controls and their operation relative to your show.

_____

_____

_____

15.0 (a) Attach a copy of the written setup, alignment and test procedures to be followed prior to the operation of the laser light show at each location (see sample check list for laser light shows in Appendix).

PROCEDURES ATTACHED_____

If not attached, explain_____

_____

_____

(b) When are these procedures performed?_____

_____

(c) What laser radiation levels are used during setup, alignment and checkout?
_____Milliwatts

(d) Is a record of the results of the setup, alignment and test procedures maintained?
YES___ NO___

NOTE: The record must include (1) sketches showing the location of the laser projector(s), operator(s), performer(s), audience, beam paths, viewing screens, wall mirrors, mirror balls, and other surfaces that may be struck by the laser beam; (2) information on scanning patterns, velocity and frequency; and (3) laser radiation levels.

16.0 What procedures are followed for notification of appropriate Federal, State and local agencies?

PROCEDURES ATTACHED _____

If not attached, explain _____

_____

What Federal, State or local agencies are notified or would be notified?

LIST OF SPECIFIC AGENCIES OR TYPES OF AGENCIES ATTACHED _____

If not attached, explain _____

_____

APPENDIX

Sample Check List for Laser Light Shows (to be submitted under 15.0 (a))

Note: In order to keep in effect your variance for a laser light show that uses class III or IV levels of laser radiation, it is essential that you maintain your show in strict compliance with the conditions of the variance. You are therefore expected to perform checks as often as appropriate to make sure that you have not departed from any of the conditions of the variance and to maintain records ready for inspection without warning to show that you have done so.

The sample shows the types of checks that should be performed during preparation for a laser light show. It is not our intention that you adopt our sample without any modification. Individual aspects of your show may make it important to add some new items and delete others. Submit your completed check list as directed by 15.0(a) and maintain records of subsequent checks.

Laser Light Show Check List and Documentation

All items must be brought to a satisfactory state before being checked off

A. Identification

1. Name of show _____

_____

2. Location of show _____

_____

3. Date(s) and time of show _____

_____

4. Operator responsible for safety of show _____

_____

5. Manufacturer of the laser light show/display product and address

_____

_____

_____

(Zip code)

_____

(Phone number)

_____

(Name and title of responsible person)

B. Equipment checks

1. Are all protective housings in place with proper tight fit?

2. Is the projector secured rigidly in place? ____

3. Before activating the laser, check that all beam shutters are operable and are left in the closed positions. ____

4. Make sure that the laser cannot be energized without the key and that key removal terminates operation. ____

5. Check that all accessory optics such as mirrors and targets are secured in place. ____

6. Energize the laser at the lowest possible power (without allowing the laser light to emerge and with shutters closed). _____

7. Confirm that all emission indicators and the emission delay operated properly. _____

8. Verify that all required labels are in place and visible on the projector:

Certification _____

Identification _____

Aperture(s) _____

Protective housing(s) _____

Warning logotype(s) _____

Alignment Checks

1. Evacuate all but essential personnel from the facility. These checks must be performed with no audience present. _____

2. Make certain that you have visual control of the entire projection space from your operating location (especially the audience space) and that areas are secured per ANSI Z136.1 standard. _____

3. Operating the laser at the lowest possible power, open the shutters and perform alignment(s). _____

4. Perform a physical survey to confirm that beams exceeding Class II will be separated from the audience by at least the minimum distances required (3 meters in vertical separation above any surface upon which the audience may stand and 2.5 meters in horizontal separation and vertical separation below audience locations for shows under continuous operator control, and 6 meters in vertical separation above any surface upon which the audience may stand and 2.5 meters in horizontal separation and vertical separation below audience locations for shows not under continuous operator control). _____

5. Review your proposed projections with venue management to be certain that the audience will not be permitted access to locations resulting in a violation of item 4 above. ____

_____. ____
(name and title of management agent with whom review was conducted)

6. Operate the projector at the power required for the show, make sure that there are no spurious projections into unintended areas and that the conditions of item 4 are maintained. Determine and record the power levels in accordance with Part 10 of your initial or model change report. ____

7. Confirm that all projectors and optics are rigidly secured and cannot be disturbed during subsequent setup operations or during the show itself. ____

8. Check for operation and proper setting of all devices related to safety including:

beam blocks ____
scanning safeguards ____
emergency stop controls ____

9. Maintain continuous surveillance of the projectors and all optics between the times of alignment and the show to be certain that the alignment of the projector and optics is not disturbed. ____

D. Measurement/parametric checks

1. List the effects to be performed

a) _____

b) _____

c) _____

d) _____

e) _____

f) Listing of additional effects attached _____

2. For each effect give:

Effect	Duration	Design power	Measured power	Identification of measuring instruments	Scan frequency	Scan amplitude

E. Administrative checks

1. List the name and title of the individual responsible for safety at the show facility

_____

_____

_____

_____

2. List those agencies you have notified of your show

_____

_____

_____

_____

Attach a copy of your notification(s)

3. Attach plan and elevation drawings showing the locations of all projectors, external optics, projections, and audience.

Note: Safety considerations mandate that you account for all specular reflections and that the operator have **visual control of all projections at all times.**

*U.S. GOVERNMENT PRINTING OFFICE: 1985-461-356:10048